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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,703	02/05/2004	William M. Colone	297912002102	5606

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MORRISON & FOERSTER, LLP
555 WEST FIFTH STREET
SUITE 3500
LOS ANGELES, CA 90013-1024

EXAMINER	
AUGHENBAUGH, WALTER	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,703	COLONE, WILLIAM M.	
	Examiner	Art Unit	
	Walter B Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/05/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Gore (US 3,962,153).

In regard to claim 42, Gore teaches a radially expandable tube consisting of extruded expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils (col. 14, lines 30-35 and col. 2, lines 52-55). Gore teaches that the tube is radially dilated to a diameter that is 2.8 times (0.56/0.20 = 2.8) the diameter of the tube prior to dilation (col. 14, line 49 to end of col. 14, see "Outside diameter" values for the unexpanded and expanded tubing in Table 8 in the last line of col. 14). While Gore teaches that the tube is sintered (col. 14, lines 55-57), the recitation "is sintered to contract said tube from said expanded diameter to a contracted diameter that is substantially the same as said original inner diameter, said tube exhibiting a radial expansion ratio of 1.0" is a method limitation that has not been given patentable weight since the method of forming the tube is not germane to the issue of patentability of the tube itself. The tube taught by Gore meets the structural limitations of the final product that is claimed: any comparison of the final product to an intermediate product (such as the claimed radial expansion ratio) is not germane to the issue of patentability of the final product. The claimed minimum ratio of expanded diameter/original diameter of the tube (i.e. "two times") is relevant only

insofar as the polytetrafluoroethylene of the prior art must be capable of expanding to the extent claimed by Applicant.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore (US 3,962,153) in view of Gore (US 4,187,390).

Gore ('153) teaches the tube as discussed above. Gore ('153) teaches that the material of the tube has a relatively high permeability to nitrogen and that controlling the degree of expansion of the material of the tube and other processing conditions makes it possible to achieve any desired permeability within the range disclosed by Gore ('153) (col. 5, lines 18-27).

Gore ('153) fails to teach that the tube is radially dilated to at least three, four and five times the diameter of the tube prior to dilation.

Gore ('390), however, discloses a radially expandable tube consisting of extruded expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils (col. 2, lines 54-57 and col. 6, lines 45-50) where any desired permeability within the range disclosed by Gore ('390) can be achieved via control of the degree of expansion of the material of the tube and other processing conditions (col. 4, line 66-col. 5, line 7). Gore ('390) teaches that the tube is stretched to 5.5 times the original length (col. 6, line 62-col. 7, line 40) (presumably length, see claims 71-76 at col. 22, lines 8-26). Therefore, one of ordinary skill in the art would have recognized to have varied the degree of radial expansion of the tube of Gore ('153) to 5.5 times as taught by Gore ('390), and to at least any other value less than 5.5, in order to achieve the desired nitrogen permeability of the tube as taught by both Gore ('153) and Gore ('390).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the degree of radial expansion of the tube of Gore ('153) to 5.5 times as taught by Gore ('390), and to at least any other value less than 5.5, in order to achieve the desired nitrogen permeability of the tube as taught by both Gore ('153) and Gore ('390).

5. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gore (US 3,962,153) in view of Marin et al. (US 5,618,300).

Gore teaches the tube as discussed above. Gore fails to teach that the tube is attached to an expandable stent. Marin et al., however, disclose a graft-stent complex comprising an expandable polytetrafluoroethylene graft (item 46) that is sutured (therefore, attached) to a pair of expandable stents (items 48a and 48b) (col. 4, lines 43-65 and Fig. 1). Therefore, one of ordinary skill in the art would have recognized to have attached the pair of expandable stents of Marin et al. to the tube of Gore and to have used the resulting structure as the graft-stent complex

of Marin et al. since it is notoriously well known to attach a pair of expandable stents to a expandable polytetrafluoroethylene tube to form a graft-stent complex as taught by Marin et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached the pair of expandable stents of Marin et al. to the tube of Gore and to have used the resulting structure as the graft-stent complex of Marin et al. since it is notoriously well known to attach a pair of expandable stents to a expandable polytetrafluoroethylene tube to form a graft-stent complex as taught by Marin et al.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
12/09/04 WBA

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

12/10/04